

TELESCOPIC PLATE SPACER (TPS™) SPINAL SYSTEM, CERVICAL

CAUTION: Humanitarian Device. Authorized by Federal law for use in the treatment of spinal metastatic disease in the cervical and/or cervico-thoracic spine (C₁-T₂). The effectiveness of this device for this use has not been demonstrated.

INDICATIONS FOR USE

The INTERPORE CROSS International Telescopic Plate Spacer (TPS) Spinal System implants are intended to replace vertebral body structures following a vertebrectomy/corpectomy of the spine for metastatic spine disease in the cervical and/or cervico-thoracic spine (C₁-T₂). The TPS Spinal System implants are intended to correct spinal alignment and stabilize the spinal operative site during fusion. TPS Spinal System implants attach to the spine anteriorly by means of their trapezoidal shape and by screws joined with a plate and spacer component.

INDIVIDUALIZATION OF TREATMENT

Patients must meet the following criteria:

1. Skeletally mature.
2. Demonstration of metastatic disease in the cervical and/or cervico-thoracic spine (C₁-T₂)
3. One or two contiguous vertebral bodies require replacement due to metastatic disease
4. Minimum life expectancy ≥ 3 months; and
5. One of the following:
 - A. Spinal instability, i.e., $\geq 5^\circ$ angulation or ≥ 3 mm subluxation or compression fracture.
 - B. Neurological deficit; compromised reflexes or sensory motor loss, or decreased fecal or urinary continence, where the patient is considered ineligible for or an inappropriate candidate for immediate treatment with (further) chemotherapy, immunotherapy, radiation therapy or steroid therapy alone.
 - C. Patient is imminently unstable and at imminent risk of neurological injury by virtue of erosive destruction of the spine, where the patient is considered ineligible for or an appropriate candidate for immediate treatment with (further) chemotherapy, immunotherapy, radiation therapy or steroid therapy alone.
 - D. Severe intractable pain, not relieved by medication, pain is > 80 on the 101 NRS Scale, where the patient refuses the morphine pump and is considered ineligible for or an inappropriate candidate for immediate treatment with (further) chemotherapy, immunotherapy, radiation therapy or steroid therapy alone.
 - E. Sole recurrence of tumor, where the patient is considered ineligible for or an inappropriate candidate for immediate treatment with (further) chemotherapy, immunotherapy, radiation therapy or steroid therapy alone.

A diagnosis of spinal metastasis may be made based on either MRI signal changes suggestive of spinal or epidural lesions, or myelogram and computerized tomography (CT) showing spinal or epidural lesions.

PRODUCT DESCRIPTION

The INTERPORE CROSS International TPS Spinal System implants function as a single construct that combines an anterior plate and an intervertebral column spacer. The TPS Spinal System implants are composed of seven components. The device consists of one (1) female chamber, one (1) male chamber, one (1) set screw, and four (4) bone screws. The TPS Spinal System implants are made from medical implant grade titanium alloy as described by ASTM Standard F-136 (Ti 6Al-4V ELI) and are available for one and two level vertebrectomies/corpectomies. A one level cervical vertebrectomy/corpectomy device telescopes in length from 22.3 mm to 29.4 mm; a two level cervical vertebrectomy/corpectomy device telescopes in length from 33.5 mm to 49.8 mm.

CONTRAINDICATIONS

None known.

WARNINGS

This device should NOT be used in the following situations:

- Anticipated survival of less than three months
- Skeletal immaturity
- Localized or systemic infection
- Severe osteoporosis

Warning: Do NOT use this device with other devices with dissimilar metals. Mixing of dissimilar metals can

accelerate the corrosion process. Stainless steel and titanium components must NOT be used together in building a construct. No components of the INTERPORE CROSS International TPS Spinal System should be used with the components from any other system or manufacturer.

PRECAUTIONS

The INTERPORE CROSS International TPS Spinal System implant must only be implanted by a fully qualified surgeon. Even with the use of TPS Spinal System implants by a qualified surgeon, a successful result in terms of pain, function, or fusion is not always achieved.

Preoperative:

- Confirm that all necessary implants and instruments are on hand for the planned surgical construct.
- Be sure that the implant components have been handled and stored carefully, protected from any damage, including corrosive environments.
- Unpack all implants and instruments and inspect for damage, including scratches or notches, and clean and sterilize prior to use in the operative field.

Intraoperative:

- The INTERPORE CROSS International TPS Spinal System Surgical Technique Manual should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots.
- Breakage, slippage, misuse or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.

Postoperative:

- The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation.
- The patient should be instructed in the limitations of physical activities that would place excessive stresses on the implants or cause delay in the healing process.
- The patient should also be instructed in the proper use of external braces or any other assist device that may be required.

POSSIBLE ADVERSE EVENTS

The INTERPORE CROSS International TPS Spinal System has not been tested in clinical trials, and there are no data available on actual adverse effects from its clinical use.

The potential adverse effects that may occur with the use of this device may be the same as those that can occur with vertebral body reconstruction surgery for metastatic disease using alternative means. These include, but are not limited to, the following device-related effects:

- Bending, loosening or fracture of the implants or instruments
- Metal sensitivity to foreign body including possible tumor formation
- Skin or muscle sensitivity
- Nonunion or delayed union
- Bone loss due to resorption or stress shielding
- Bone fracture at, above, or below the level of surgery
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
- Inability to resume activities of normal daily living

In addition, surgery or surgical approach related effects include the following:

- Skin breakdown and/or wound complications
- Bursitis
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Dural tears
- Cerebral spinal fluid leakage
- Nerve or vascular damage due to surgical trauma, including loss of neurological function
- Radiculopathy
- Paralysis

- Urological and/or reproductive system compromise including sterility, impotency and/or loss of consortium
- Pain or discomfort
- Stroke
- Death.

INSTRUCTIONS FOR USE

SURGICAL TECHNIQUE:

After appropriate patient selection criteria has been applied, the following surgical technique will apply:

1. Standard anterior Cloward approach for tumors at C₄-C₇, or modified Cloward approach for the cervico-thoracic junction T₁-T₂, or for tumors at C₃ an extra-pharyngeal (McDonnell) approach is recommended to expose the surgical level.
2. X-ray or fluoroscopy to confirm the surgical level.
3. Place the retractors beneath the longus colli muscles.
4. Perform vertebrectomy/corpectomy at the diseased level(s) with a discectomy above and below the vertebrectomy/corpectomy. Use the available templates to gauge the width of the vertebrectomy/corpectomy defect, seen in the A/P view, to ensure the vertebrectomy/corpectomy is wide enough to accept the male and female chambers.
5. Remove the cartilaginous end plates, but preserve the cortical end plate of the adjacent vertebrae.
6. Fill the male component of the TPS device with bone graft material.
7. Assemble the male and female components to a length which closely approximates the vertebrectomy/corpectomy defect, and finger tighten the set screw. The set screw will draw the teeth of the male component to the teeth of the female component, maintaining the desired device length.
8. Continue filling the assembled device with bone graft material.
9. With the distractor, place the TPS device into the vertebrectomy/corpectomy defect with the male chamber cephalad and the female chamber caudal. Ensure that the flanges of the device are flush on the adjacent vertebrae. A distractor pocket is provided in the bone flanges of the male and female chamber. The distractor uses the pockets to gradually distract the device, by advancing the teeth of the male component along the teeth of the female component, until cervical alignment and/or lordosis has been restored.
10. Loosen the set screw and distract the device to achieve compression between the implant and the adjacent vertebral end plates. Continue distracting until normal spine contour or lordosis is restored. Tighten the set screw to maintain the desired length of the TPS device.
11. Pack additional bone graft material into the device through the bone graft holes.
12. Adjust the variable drill guide to the appropriate screw length. Thread the drill guide into the screw guide and hand drill a 2mm pilot hole into the adjacent promontory. The drill guide prevents the drill from advancing past the desired hole depth. If the cortical promontory of the vertebra is nonexistent or of poor quality, thread the drill guide into one of the two optional screw holes in the bone flange and drill the 2mm pilot hole. These optional screw holes may also be used if limited exposure or anatomical interference makes the screw guides unattainable with the drill guide.
NOTE: Due to screw interference, it is impossible to use both the screw guide holes and the optional screw holes to secure the bone flange. It is possible, however, to use one screw guide hole and the opposite optional screw hole to secure the bone flange to the vertebrae.
13. Remove the drill guide and thread the temporary lag screw through the screw guide and into the adjacent vertebra. It is important that the flanges of the device are flush on the adjacent vertebrae during securing of the temporary lag screws.
14. Repeat Steps 12 and 13 for the remaining temporary lag screws. The temporary lag screws, a total of three, will assist in holding the implant flush to the adjacent vertebra during insertion of the bone screws. For the last screw hole, adjust the variable drill guide to the appropriate screw length, thread the drill guide into the screw guide and hand drill a 2mm pilot hole into the adjacent promontory.
15. Remove the drill guide and thread the bone screw through the screw guide and into the adjacent vertebra. Tighten the bone screw until the threads of the bone screw lock into the threads of the device. Again, it is important that the flanges of the device are flush on the adjacent

vertebrae during securing of the bone screws. When the bone screw is secured, the top of the screw head will be flush with the screw guide. The self tapping fluted 4mm x 18mm bone screw is used with the screw guide holes. Through the optional screw holes it is possible to engage the anterior and posterior cortical bone of the adjacent vertebrae. A total of five bone screws of varying lengths are available to achieve bi-cortical purchase. These 4mm bone screws come in lengths of 14, 16, 18, 20 and 22mm. The bi-cortical screws have blunt tips to minimize injury to the spinal cord should the screws exit the posterior cortical bone. The bi-cortical screws are also secured into the device through the threaded locking mechanism.

16. Remove one lag screw at a time and thread the bone screw through the screw guide and into the adjacent vertebra. Tighten the bone screw until the threads of the bone screw lock into the threads of the device. Again, it is important that the flanges of the device are flush on the adjacent vertebrae during securing of the bone screws. When the bone screw is secured, the top of the screw head will be flush with the screw guide. Repeat this step for the two remaining screw holes.
17. With the distractor, apply a counter torque while tightening the set screw. Tighten until the head of the set screw shears off at approximately 4 N-m, locking the male and female components together.
18. Obtain an intraoperative lateral x-ray to confirm proper placement and to verify that cervical alignment and/or lordosis has been restored.
19. Recheck the tightness of all bone screws and verify that the top of the bone screws are flush with the screw guides.
20. Irrigate the wound, remove the retractors, inspect for hemostasis, and irrigate thoroughly.
21. Standard two layer wound closure, drain per surgeon preference.

NOTE: The INTERPORE CROSS International TPS Spinal System Surgical Technique Manual should be carefully followed. It supplies important information on proper usage of the implants and instruments. For a more detailed description of the surgical technique and supporting photographs of the major steps, please refer to the INTERPORE CROSS International TPS Spinal System Surgical Technique Manual.

STERILITY

The INTERPORE CROSS International TPS Spinal System is provided NONSTERILE. All packaging should be sealed and intact upon receipt. If the package or product is damaged, it should not be used and should be returned immediately.

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycle has been validated:

Method:	Steam
Cycle:	Gravity
Temperature:	250°F (121°C)
Exposure Time:	60 minutes

NOTE: It is recommended to dry and/or cool the parts to prevent condensation after the steam cycle.

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Telescopic Plate Spacer (TPS™) Spinal System Patient Brochure

CAUTION: Humanitarian Device. Authorized by Federal law for use in the treatment of spinal metastatic disease in the cervical and/or cervico-thoracic spine (C₃-T₂). The effectiveness of this device for this use has not been demonstrated.

Introduction

The patient information contained in this brochure is designed to help you make an informed decision about treatment for the tumor(s) in the cervical portion of your spine located in your neck. Your doctor has determined that the tumor in your neck has caused one or more of the bones in your neck to become unstable. Your doctor has proposed that you have the tumor(s) and one or two of the affected vertebral bodies (bones) in your cervical spine removed.

Metastatic spinal disease (tumors that have spread from another location in the body) such as yours, can result in broken bones and invasion of the epidural spaces (area around the spinal cord) if it is not treated. This can result in compression (pinching) of the spinal cord and nerve roots leading to severe pain, weakness, numbness, and abnormal function of the bladder or bowel. One way to treat tumors in the spine is with surgery as suggested by your doctor. The type of surgical treatment depends on several things including the type of tumor, where it is located in your spine and whether or not your spinal cord and nerve roots are compressed.

Device Description

The TPS Spinal System is designed to stabilize and align the cervical spine, reduce pain, and increase a patient's ability to function following removal of tumors and affected bones in the cervical spine. The TPS Spinal System consists of two metal implants (a male and a female chamber) that fit together to act as a spacer. The implants are placed into your neck after the tumor and affected bones have been removed. The implants are held in place in your neck with bone screws. Each implant contains a hollow chamber that can be packed with bone graft material.

Benefits

The TPS Spinal System is designed to straighten and restore the height of your cervical spine and to hold it in place (stabilize it) until the spine has healed (fused). The TPS device has a flange (extension) that prevents the device from touching or pushing on the spinal cord. The screw guides allow a safe screw placement that will avoid the nerves and spinal cord in the neck. Bone from a

bone bank or a bone graft substitute can be used with this device instead of bone taken from your hip. The device is faster to use than the usual methods of fixing the spine which means less time in the operating room. The TPS Spinal System is designed to reduce your pain and allow you to increase your activity level and quality of life following your surgery.

When TPS Spinal System Implants Should Not Be Used

Patients with certain conditions should not have the TPS Spinal System implanted. These conditions include:

- Anticipated survival of less than three months
- Skeletal immaturity
- Localized or systemic infection
- Severe osteoporosis

Surgery

You should select a doctor that is familiar with this type of surgery. During your surgery, your doctor will make an incision (cut) in your neck to expose the tumor. The tumor and affected bones in the cervical spine of your neck will be removed and replaced with the TPS Spinal System implants. Your doctor will put bone graft material into the hollow portion of the implant. When your doctor finishes the procedure, your incision will be closed.

After Surgery

It is important that you follow your doctor's instructions carefully to recover from surgery as quickly as possible. You will be asked to see your doctor periodically after surgery for follow-up visits. There may be some limits on your physical activity. You will have to avoid any activity that will put stress on your implants or cause a delay in your healing. You may also have to wear a neck brace. No additional tests or procedures will be required other than those that are typical for this type of spinal surgery.

Possible Complications

Talk to your doctor for expected results following surgery. Surgery of any kind is not without risk. Complications may occur and may affect the outcome of your treatment. These complications are the same types of complications that may occur with any spinal surgery and include, but are not limited to:

Device related effects, such as

- Bending, loosening or fracture of the implants or instruments
- Metal sensitivity to foreign body including possible tumor formation
- Skin or muscle sensitivity
- Nonunion or delayed union

- Bone loss due to resorption or stress shielding
- Bone fracture at, above, or below the level of surgery
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
- Inability to resume activities of normal daily living

Surgery or surgical approach related effects:

- Skin breakdown and/or wound complications
- Bursitis
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Dural tears
- Cerebral spinal fluid leakage
- Nerve or vascular damage due to surgical trauma, including loss of neurological function
- Radiculopathy
- Paralysis
- Urological and/or reproductive system compromise including sterility, impotency and/or loss of consortium
- Pain or discomfort
- Stroke
- Death.

Although this treatment may help relieve your pain and stabilize your spine, spinal surgery is not without risks. Please consult with your doctor about the types of possible complications related to this type of spinal surgery

Other Available Treatments

There are other alternatives that could be considered in your case. These alternative treatments would include: bone cement or bone graft to replace the diseased bone with or without a plate in the front or the back of the spine (through another operation through the back). The bone used is either taken from your hip, rib or from a bone bank or is a bone graft substitute. The plate used is metal and fixed to the spine with metal screws. This plate holds the bone graft in place to allow it to heal (fuse).

Comments

If you have questions or need additional information about the TPS Spinal System, please call or see your doctor.

Illustration of the Telescopic Plate Spacer (TPS)
Spinal System Implants

